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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,143	07/31/2001	Leandro Christmann	AVI 008	2824

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AVIGENICS, INC.
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EXAMINER

WILSON, MICHAEL C 4

ART UNIT PAPER NUMBER

1632

DATE MAILED: 03/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/919,143

Applicant(s)

CHRISTMANN, LEANDRO

Examiner

Michael C. Wilson

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-8, 10, 12 and 14-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9, 11, 13 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other: _____

DETAILED ACTION

Applicant's election of Group II, claims 9, 11, 13 and 18, drawn to methods of making transgenic avians or cloning avians, in Paper No. 5 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-8, 10, 12 and 14-17 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 5.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9, 11, 13 and 18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed is directed toward microinjecting an exogenous nucleic acid into an avian embryo and obtaining a chick. The nucleic acid may be in the form of spermatozoon or an isolated cell nucleus (claim 11). The claims encompass making transgenic avians and cloning avians. When making transgenics, the only enabled

purpose for the method is to obtain a germline chimeric chick, i.e. a chick that carries the exogenous nucleic acid in its germ cells and passes the nucleic acid on to its offspring. When cloning, the only enabled purpose for the claimed method is to obtain a viable offspring that has the donor nucleus. Merely transferring exogenous nucleic acids into a recipient embryo does not have an enabled use without obtaining a germline chimera or a clone. The specification teaches the avians produced by the method claimed would be used as protein bioreactors (pg 3, line 11).

The specification summarizes methods of obtaining transgenic mice (pg 2-3) known in the art at the time of filing. However, methods of making transgenic mice do not correlate to making transgenic avians (Proudman, 2001, "The quest for transgenic poultry: birds are not mice with feathers" Biotechnology in Animal Husbandry, Vol. 5, Kluwer Academic Publishers, pg 283-299). Proudman summarizes methods of making transgenic mice on pg 284 and concluded, "this technology can only be applied in the mouse." Proudman states "[t]he use of similar techniques to produce transgenic poultry is hampered by major biological differences in the structure and development of mammalian and avian eggs" (pg 284, 2nd full para.).

More specifically, the specification summarizes methods of making transgenic avians by introducing exogenous DNA into avian eggs known in the art (pg 3-5). Proudman also reviews the progress achieved in the field of making transgenic poultry, and states, "[t]he technique of microinjection that has proven successful in other species is not directly applicable to avian species" (pg 284, last sentence). That is because of the difference between the mammalian and avian early embryo (pg 285, first two para.).

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The specification does not teach how to obtain germline chimeras using microinjection.

The specification does not correlate methods known in the art capable of producing germline chimeras to the method of microinjection described in the specification such that one of skill could produce a germline chimeric chick. Without such guidance, it would require one of skill undue experimentation to make a germline chimeric avian using microinjection as described in the specification. Therefore, the specification does not overcome the unpredictability in the art by teaching how to obtain a germline chimeric chick by microinjection.

The specification contemplates removing the nucleus of an avian egg (pg 37, Example 3) and transplanting a donor nucleus into the egg (pg 39, Examples 5 and 6), i.e. cloning. The art at the time of filing did not teach how to clone avians. Therefore, it was unpredictable how to clone avians at the time of filing. The specification does not teach obtaining a viable offspring. The specification does not adequately correlate methods known in the art capable of cloning to the method of microinjection described in the specification. The specification does not correlate the structure of mammalian embryos capable of cloning known in the art to avians embryos such that one of skill could use mammalian cloning methods to clone avians. Without such guidance it would require one of skill undue experimentation to use microinjection to make avians that carry the donor nucleus. Therefore, the specification does not overcome the unpredictability in the art by providing adequate guidance for one of skill to clone an avian.

The specification describes methods of transferring exogenous nucleic acids into chickens but does not teach transferring exogenous nucleic acids into other birds (claim 13). The specification does not correlate the structure of chicken embryos to any other bird embryos. Without such guidance it would require one of skill undue experimentation to use microinjection to make any avians as broadly claimed. Therefore, the claims should be limited to chickens.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson

A handwritten signature in black ink, appearing to read 'M. Wilson', with a long horizontal flourish extending to the right.